D6.1 Xt-EHR commenting form Industry X-Net

EU Member State (MS) ISO 3166 two-letter country code **or "EU"** for European stakeholder organisations	**Section/ Subsection** number	**Comment** (justification for change)	**Proposal how to resolve comment**, proposed change
Industry X-Net	2.1 Scope	**X-Net #1**: The deliverable does not define parameters for searching/requesting a Patient Summary. As illustrated in our other feedback, parameters will be needed to support different use cases and clinical needs.	Work with SDOs (HL7 EU, IHE Europe) to ensure the technical specification includes search parameters to support the required use cases. These should include (but not be limited to): - A way to indicate if documents returned should be automatically generated upon request, or created previously (either automatically or manually) - Date range, in the case of documents created previously - A way to indicate if the audience of the document will be a healthcare provider or a patient or proxy. - A period of care that represents the time of service that is being documented. The period search parameter specifies an interval which the time of service overlaps. In Document Sharing nomenclature, this query parameter represents from/to parameters for the serviceStartTime and serviceStopTime in the Document Entry - A Category that is set to "summary" to distinguish it from reports, precriptions, etc. This ensure a robust search when combined with a Practice Setting code. - A Practice Setting code that characterizes the source of the PS (intensive care, general practice, emergency medicine, etc.). See MHD Comprehensive Search Parameters for a complete list.
Industry X-Net	8.2.1 Create the Patient Summary	**X-Net #2:** There is a use case for an "Automatic (on-the-fly) creation of Patient Summary". and two use cases for "Patient Summary sharing on a national scale" and Patient Summary sharing on a cross-border scale. The "Automatic (on-the-fly) creation of Patient Summary" currently states:	The intent of the authors is not clear, and as a result it is not clear how the requester may have a choice of PS to access or if this is left entirely to the responding source. In the case of cross-border data exchange, providers should be able to request for patient summaries irrespective if those are single source or multiple sources, created

		-a- Creation is triggered upon detection of a new PS Record (a new updated version of PS is created), The -a- case is not clear in terms of input: indeed, what is a "new PS Record". Is it the creation of a manually created PS of the previous use case, or is it the fact that new information becomes available (outside of present use case). In all cases a PS is created at a point in time and available for sharing. **-b- Creation is triggered upon request** for PS (an up-to date PS is created upon query/retrieve) by health professional or, where applicable, the patient. The -b- case is quite clear. A PS is created at the time of request and is shared. In addition a copy needs to be stored for "for traceability and look-up in case of the need to legal backward reconstruction of that specific snapshot". **-c- Scheduled creation / update** of PS (regular schedule for system procedures for collecting relevant records and generation of PS) The -c- case is not clear in terms of output. Is a PS created as a point in time summary? At a later point in the schedule, when a new PS is created, is the previously created PS replaced by the new version? It appears that the above can be simplified by removing the points where the use cases are confusing and to distinguish the "1-PS content creation" process from the "2-Publication of the PS". 1-how the content of a PS can be created: either **1a-automatically on the fly** by a source (is it an EHR system or a national aggregation service?) **1b - at a point in the past** in relationship with care provided. and 2- if the existence of a PS is being	automatiacally/on-the-fly (on-demand at the time of request), or if they have been created in the past. This implies that the requester need to have search parameters to filter its request (**See comment X-NET #1**). We recommend leveraging the IHE MHD Profile and its "on-demand document" capability: See: 2:3.67.4.2.2.1.2 Support for On-Demand Documents XDS introduced the concept of a On-Demand Document Option, and is explained in the Use Cases Summary. The use of On-Demand Documents allows for documents that would be produced for a specific patient with content assembled at the time of processing the document consumer retrieve request. On-Demand Documents are indicated in the DocumentReference by the DocumentReference.content.attachment with an absent .hash and .size element. For more background on On-Demand Documents. There is no need to declare an On-Demand Documents Option in MHD. It is also strongly advised to rely on the analysis perfromed in the IHE sIPS Profile that discusses how the FHIR IPS may shared when created either on-demand or at a point in time.

		made available (the PS can be either 1a or 1b above).	
Industry X-Net	8.2.2 Request of the Patient Summary	**X-Net #3**: The "Request for the Patient Summary by the Patient or patient's representative" use case mentions the need for information to "support patient readability," and there are other reasons a patient may not have access to the same data elements a provider would. For instance, an EHR could contain results or future appointments that the patient should discuss with their provider before seeing them electronically (as in the case of suspected cancer). The EHR might have functionality to produce a Patient Summary document without these results when requested by the patient, but to include the results when requested by a provider. The use case and specifications for the Patient Summary should support this possibility.	Include a search/request parameter to indicate the requester/intended audience of the Patient Summary. Clarify whether and how a patient- or proxy-facing Patient Summary should differ in content than one intended for providers.
Industry X-Net	8.2.2 Request of the Patient Summary	**X-Net #4:** Clarify requirements about language translation for cross-border exchange. Language translation of non-coded data carries risks of changing the meaning in clinically important ways.	We recommend that langauge translation not be performed by producers or exchangers of Patient Summary documents.
Industry X-Net	8.2.2 Request of the Patient Summary	**X-Net #5:** Clarify handling of optional sections. When Patient Summary documents are exchanged via NCPs, optional sections should be passed through and not lost, even if an NCP does not support processing those sections. This is not what current NCPs are doing but it seems to be an important evolution in order to leverage the benefit of EHDS across countries.	Indicate in the cross-border use case that there is a functional requirement to pass through all sections in the document and they are not lost. Work with WP8 and the SDOs (HL7 EU, IHE Europe) to ensure the technical specification to ensure that requirements for Exchangers reflect this functional requirement.
Industry X-Net	8.2.3 Update the Patient Summary	**X-Net #6:** The concept of updating a PS shown here causes confusion. A PS - as a summary - is a snapshot and cannot be updated but is replaced by a newer version. If the intention of this use case is to define how a central repository	Honestly show the problems arising from different parties with different levels of access to data providing different patient summaries of the same patient rather than claiming there could be only one patient summary that is constantly being updated. Ideally, also extend the guide with as much guidance on how to deal with these issues as possible.

		should be updated upon receiving new information in the form of a Patient Summary, note that this newer version only contains information that was available to the party constructing it, so different information about a patient may be available in different PSs from different parties. Correctly interpreting, deduplicating, and consolidating data from multiple sources is a complex and risky task.	
Industry X-Net	9.3.2 About Patient Summary data models	**X-Net #7:** The "implementation of only parts of the PS" is not consistent with the Patient Summary acting as a document, and in general acting as a "summary." The full context and nuance of variations in use case can't be consistently communicated to all future viewers of the document, especially across borders.	We suggest more strictly setting expectations for EHDS-relevant use cases (cross-border exchange and patient access to data) that the Patient Summary should be intended as a full summary of data for a patient in a given system at a give time, not be used as a partial document for queries for only certain data types or content. For those use cases that need certain data type or partial content we suggest accessing individual resources or developing implementation guides specific to the use case.
Industry X-Net	10.1 Annex I Patient summary data sets	**X-Net #8:** The presentedForm element is redundant with each section's narrative element.	Remove the presentedForm element generally and from each section.
Industry X-Net	10.1.8 Vaccination/prophylaxis model	**X-Net #9:** Allow for not-completed vaccinations (vaccinations not given at all) to be represented in the vaccination section, as this can be important for patient care (for instance, if vaccinations were deferred due to a contraindication).	Update the model to allow for vaccinations that were not administered. - dateOfVaccination would not be 1..1 - a status / statusReason field would make sense to explain these entries
Industry X-Net	9.3.4 Summary overview of all sections	**X-Net #10:** It is not clear what is meant by 'result' observations and other observations (vital signs?) seem to be missing.	Clarify what is meant by 'result' observations here.
Industry X-Net	9.3.5 Detailed models	**X-Net #11:** Alerts are usually about something that is also registered.	Consider allowing a reference to at least an Allergy or a Problem/Condition to be used in stead of a code or textual description.
Industry X-Net	9.3.5 Detailed models	**X-Net #12:** After using a model similar to this one for some time in The Netherlands, it was concluded there is no role for the severity of a specific reaction. It is easily confused by the criticality of the allergy and the manifestation is often the single determinant of the severity.	Consider removing the severity of a reaction.

Industry X-Net	9.3.5 Detailed models	**X-Net #13**: An AnatomicalLocation seems to be missing from this model for a Problem/Condition. Not all SNOMED CT concepts that could be used for recording a diagnosis that could occur in multiple locations, imply a specifc location.	Consider adding the AnatomicalLocation to the model for a problem/condition.
Industry X-Net	9.3.5 Detailed models	**X-Net #14**: It is not clear what is meant by the difference between medication reason and medication reason text.	Clarify what is meant by the difference between medication reason and medication reason text. If this is meant to show that the reason for prescription of medication could either be coded or registered as unstructured text, consider allowing this in general rather than specifically for this field.
Industry X-Net	9.3.5 Detailed models	**X-Net #15**: Attributes of a device seem to be missing here, which seems to imply device specifics are intended to be shared as a single string. This seems insufficient considering e.g. identifiers for implants, which are crucial in case safety warnings are issued.	Consider specifying attributes to describe a device, including not just a description but also an optional identifier at the very least.
Industry X-Net	9.3.5 Detailed models	**X-Net #16:** A reason for an immunisation seems to be missing.	Consider adding an attribute to EHDSImmunisation to describe the reason for immunisation.
Industry X-Net	9.3.5 Detailed models	**X-Net #17**: A route and anatomicalLocation of administration seem to be missing in the model for Immunisation, which could be relevant in case of e.g. complications.	Consider adding an attribute to EHDSImmunisation to describe how and where an immunisation was administered.
Industry X-Net	9.3.5 Detailed models	**X-Net #18**: As compared to EHDSPregnancyHistory EHDSCurrentPregnancy seems to be missing an attribute to describe the number of children/fetuses.	Consider adding an attribute to describe the number of children/fetuses for a current pregnancy.
Industry X-Net	9.3.5 Detailed models	**X-Net #19**: It is not clear what is meant by 'Current Pregnancy Status'. If this is meant to say whether a patient is currently pregnant, this does not seem to be the right way to model this as the other attributes are not applicable if there is no pregnancy.	Clarify what is meant by 'Current Pregnancy Status'. If this is meant to state whether a patient is currently pregnant, consider taking this out of the model for a pregnancy as there is no pregnancy if the patient is not pregnant.
Industry X-Net	9.3.5 Detailed models	**X-Net #20:** In emergencies, it can be crucial to be able to look up whether a patient wants to be resusitated at the very least. This requires structured exchange of whether a TreatmentDirective or	Consider adding attributes to exchange in a more structured way whether a directive permits or denies a treatment and what treatments it applies to.

		AdvanceDirective permits or denies the treatment is about, as well as what treatment that is.	
Industry X-Net	9.3.5 Detailed models	**X-Net #21:** A CarePlan can consist of multiple activities.	Model that a CarePlan can consist of more than just one activity.